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Bard Access Systems, Inc.
5425 W. Amelia Earhart Drive
Salt Lake City, UT 84116
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K000901

BARD

SECTION 11

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

11.1 Submitter Information:

Submitter Name:	Bard Access Systems, Inc. (Division of C. R. Bard, Inc.)
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ex 5418
Fax Number:	(801) 595 5425
Contact Person:	Michaela Rivkowich
Date of Preparation:	May 26, 2000

11.2 Device Name:

	Poly Per-Q-Cath® PICC Poly Per-Q-Cath® Midline
Trade Name:	Poly Per-Q-Cath® PICC Catheter Poly Per-Q-Cath® Midline Catheter
Common/Usual Name:	Poly Per-Q-Cath® PICC (Peripherally inserted Central Venous Catheter) Poly Per-Q-Cath® Midline (Peripherally inserted Midline catheter)
Classification Name:	Long Term Intravascular Catheter (80 LJS)

11.3 Predicate Device Name:

	Per-Q-Cath® PICC Per-Q-Cath® Midline
Trade Name:	Per-Q-Cath® Catheter Per-Q-Cath® Midline

11.4 Device Description:

The Poly PICC and Midline catheters are open-ended catheters that are made of Tecoflex material with 20% barium sulfate for radiopacity. The Tecoflex material is stiffer during initial placement and then softens after placement in the body.

The proximal end of the Poly PICC and Midline catheters consists of a rigid polyurethane hub (female luer lock connector) and a strain relief (catheter stepped hub). The strain relief is an addition of wall thickness at the exit site and has been added to the design to help enhance the external part of the catheter that may be exposed to chemicals, solvents, and kinking. The catheter can be inserted up to the "0" mark on the strain relief, which is sized to the exit site.

In addition, the proximal end of the dual lumen (DL) Poly PICC catheter consists of a bifurcation that is molded onto the catheter. The extension legs of the DL Poly PICC catheter are made of Tecothane material and contain slide clamps. The proximal ends of the single lumen (SL) Poly PICC and Midline catheters consist of a silicone oversleeve that is assembled onto the catheters. Both the bifurcation and the silicone oversleeve are ergonomically shaped (external) so they lie flatter on the body.

Prior to packaging, the stiffening stylet is preloaded into a vendor-supplied T-Lock connector that is attached to the proximal end of the catheter. The T-Lock connector has a flushing leg and a stylet seal.

11.5 Intended Use:

The Poly **Per-Q-Cath** PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. The Poly **Per-Q-Cath** Midline catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (See Contraindications) For blood therapy, it is recommended that a 4 French or larger catheter be used.

11.6 Technological Characteristics Summary

11.6.1 Does the new device have the same indication statements?

Yes. The Poly Per-Q-Cath® PICC and Midline have the same indication for use as the predicate Per-Q-Cath® PICC and Midline. The Poly Per-Q-Cath PICC and the predicate Per-Q-Cath PICC catheters are indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. The Poly Per-Q-Cath Midline and the predicate Per-Q-Cath Midline catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (See Contraindications) For blood therapy, it is recommended that a 4 French or larger catheter be used.

11.6.2 Does the new device have the same technological characteristics, e.g. design, material, etc.?

The answer is no, not in all respects. The principles of operation and basic design are equivalent for both the Poly Per-Q-Cath® PICC and Midline catheters and the predicate Per-Q-Cath® PICC and Midline, K954104 and K954422. The Poly Per-Q-Cath® PICC and Midline catheter material is Tecoflex, the same material as that of the Per-Q-Cath® Midline, K954422, with a reduction of barium sulfate loading from 40% to 20%. The proximal, external connection is similar in design for both catheters. There has been an addition of a strain relief to increase the wall thickness at the exit site and to help enhance the part of the catheter that is exposed to chemicals, solvents, and kinking.

The Poly Per-Q-Cath® PICC and Midline catheters contain a hydrophilic coated stainless steel stiffening stylet.

11.6.3 Could the new characteristics affect safety or effectiveness?

Yes. All the above unique features could affect the safety or effectiveness of the device.

11.6.4 Do the new characteristics raise new types of safety or effectiveness questions?

No. The safety and effectiveness questions are the same for all PICC catheters.

11.6.5 Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's draft "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters," dated 3/16/95 was used to evaluate the devices' performance.

Biocompatibility meets the requirements of ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing: and the FDA Modified ISO 10993 Test Profile. Testing was done in accordance with the Good Laboratory Practices (GLP) regulations.

11.6.6 Are performance data available to assess effects of new characteristics?

Yes. Bench testing was performed on the Poly Per-Q-Cath® PICC and Midline catheters according to the FDA's draft "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters," dated 3/16/95. The results of the FDA guidance testing were compared to the predicate silicone Per-Q-Cath® catheters. The test results met the requirements. In addition, competitive product evaluation was performed comparing the BAS Poly Per-Q-Cath® PICC's to Luther Medical's PICC catheters.

Biocompatibility meets the requirements of ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing: and the FDA Modified ISO 10993 Test Profile. Testing was done in accordance with the Good Laboratory Practices (GLP) regulations.

11.6.7 Do performance data demonstrated equivalence?

Yes. Performance data demonstrate that the Poly Per-Q-Cath® PICC and Midline catheters are substantially equivalent to the predicate Per-Q-Cath® PICC and Midline catheters. The biocompatibility test requirements have been satisfied.

Based on FDA's decision tree, the Poly Per-Q-Cath® PICC and Midline catheters are substantially equivalent to the predicate device, Per-Q-Cath® PICC, K954104, cleared for market November 21, 1995 and Per-Q-Cath Midline, K954422, cleared for market December 15, 1995.

11.6.8 Performance Data (if applicable)

Testing was performed using the FDA's draft "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters," dated 3/16/95.

Catheter guidance tests performed:

- Dimensions
- Flow rates
- Tensile strength of catheter body
- Tensile strength of catheter body to hub attachments
- Catheter stiffness
- Catheter elongation
- Leakage at hub
- Catheter burst pressure (positive internal pressure)

- Catheter collapse (negative internal pressures)
- Catheter flexural fatigue tolerance
- Radiopacity
- Priming Volume

Additional tests performed:

- Stylet dimensions
- Stylet removal
- Stylet hydrophilic coating durability
- Stylet tab tensile testing
- Simulated use testing (Competitive Product Evaluation of BAS Poly PICC to Luther PICC catheter)

Catheter guidance test not performed:

- Catheter tip (disal) attachment strength (not applicable; there is no attachment to the distal tip)

The Poly Per-Q-Cath® PICC and Midline catheters meet all the acceptance criteria of the testing performed and, based on FDA's decision tree, are substantially equivalent to the predicate device the Per-Q-Cath® PICC catheters, K954104, cleared for market on November 21, 1995 and Per-Q-Cath® Midline catheters, K954422, cleared for market December 15, 1995.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2000

Mr. Michael Rivkowich
Regulatory Affairs Specialist
Bard Access Systems, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K001901
Trade Name: Poly Per-Q-Cath PICC Catheter, Model 3236100 and Poly Per-Q-Cath Midline Catheters
Regulatory Class: II
Product Code: LJS
Dated: August 22, 2000
Received: August 23, 2000

Dear Mr. Rivkowich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION(S) STATEMENT*

I state in my capacity as Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the following devices, Poly Per-Q-Cath® PICC and Poly Per-Q-Cath® Midline catheters are indicated for the following:

The Poly Per-Q-Cath® PICC is indicated for ~~short or long~~ long term peripheral access ~~to~~ the central venous system for intravenous therapy and blood sampling. The Poly Per-Q-Cath® Midline catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (See Contraindications) For blood therapy, it is recommended that a 4 French or larger catheter ~~be~~ used.

Michael Rivkowich
Signature of 510(k) Submitter

Michaela Rivkowich
Printed Name of Submitter

6/7/00
Date

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Concurrence of Office of Device Evaluation

K001901
510(k) Number

X Prescription Device

Division Sign-Off
Office of Device Evaluation

Irene Naveau for P&C 9/19/00
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number

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